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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/069,242
Filing Date: June 18, 2002
Appellant(s): GILCHRIST ET AL.

Douglas E. Denninger
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 30, 2005 appealing from the Office action mailed May 3, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,748,121	Beaver et al	5-1988
5,811,302	Ducheyne et al	9-1998
WO 98/54104	Gilchrist et al	12-1998

Burnie et al., "Controlled Release Glasses (C.R.G.) Ffor Biomedical Uses", Biomaterials Vol 2, pp 244-246 (1981).

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

Claims 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is confusing and unclear as to the process required by reciting only a single step of providing a substrate. More would be required to perform the process than merely providing the substrate of claim 1. It is uncertain as to the relationship of the tissue to the substrate and cells of

claim 1. Is the substrate combined with tissue and culturing carried out, or are some other steps carried out.

Claim 19 is confusing and unclear in not having antecedent basis for an aqueous medium in line 2. It is uncertain as to the relationship of the aqueous medium to the tissue and substrate in claim 18, and as to steps used to deliver the metal ions or boron.

Claim Rejections - 35 USC § 103

Claims 1, 2, 4-7, 9, 10, 12, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burnie et al in view of Gilchrist et al, and if necessary in further view of Beaver et al.

The claims are drawn to a cell culture growth substrate comprising a water-soluble glass matrix having at least a portion of its surface coated with living cells and containing at least one metallic ion or boron-containing compound capable of conferring antimicrobial protection or enhanced cell growth, or both.

Burnie et al disclose using a water-soluble P_2O_5-containing controlled release glass (C.R.G.) substrate in monolayer cell culture (page 244 under "BACKGROUND", and paragraph bridging pages 244 and 245). The glass can be in a physical form suited to a particular requirement such as rod, powder, foam, fibre or

woven cloth (page 244, right col, last complete paragraph). Burnie et al disclose (page 246, right col, under "CONCLUSION") that the C.R.G. had no cytotoxic effect in tissue culture, and the C.R.G dissolved *in vivo* allowing normal bone healing and repair. The water-soluble glass of Burnie et al is the same as presently claimed except for containing a metallic ion or boron-containing compound capable of conferring antimicrobial protection or enhanced cell growth, or both.

Gilchrist et al disclose water-soluble P_2O_5-containing glass fibre or wool (page 4, line 15, page 7, line 36, page 8, lines 27-29) having biological application (page 4, line 5) containing a boron compound (page 8, lines 8-20) and silver ions (page 9, lines 8-13) for controlled release of the silver (paragraph bridging pages 9 and 10). The glass can deliver silver to an aqueous medium at a rate to maintain silver ions in the aqueous medium at not less than 0.01 parts per million and not greater than 10 parts per million (page 9, lines 28-31). The glass can provide sustained release of metal at a wound site (page 1, lines 18-20), and the glass fibres are suitable for orthopaedic implants and tissue engineering applications (page 17, lines 20-21). The glass can have antimicrobial application (page 16, line 2) and added MgO is disclosed as an anti-microbial (page 15, line 10).

Beaver et al disclose immobilizing biochemically active material such as cells (col 3, lines 17-23) on porous glass fibers prepared from a composition containing silica, boric oxide, alkali metal oxide and aluminum oxide (paragraph bridging cols 5 and 6).

It would have been obvious to provide in the water-soluble glass used by Burnie et al for monolayer cell culture a metal ion for controlled release and a boron compound to obtain the function of the metal ion and boron compound as obtained by Gilchrist et al when preparing water-soluble glass containing a metal ion for controlled release and boron compound for use as an implant and tissue engineering applications. Gilchrist et al suggest MgO as an anti-microbial, and silver ions for controlled release, and it would have been obvious to put these ions in the glass of Burnie et al for controlled release to obtain an anti-microbial effect of Mg and the effect of Ag. The glass of Burnie et al is intended for use as an implant (page 246, right col, under "CONCLUSION"), which is a use disclosed by Gilchrist et al (page 17, lines 20-21). The present specification (page 7, lines 13-17) discloses silver and magnesium ions as being ions that can be present in the claimed glass. If needed, Beaver et al would have further suggested boron in the glass of Burnie et al from disclosing preparing glass for immobilizing

cells containing boron (boron oxide) (col 6, line 3). Monolayer culture as disclosed by Burnie et al will result in the glass being coated with cells. The conditions of dependent claims would have been matters of choice depending on individual preference in view of the disclosures of the references. The glasses of Burnie et al and Gilchrist et al contain phosphorus pentoxide as in claim 5, which are a phosphate glass as in claim 4 as disclosed by Gilchrist et al (page 9, line 8-9). The glasses of Burnie et al and Gilchrist et al also contain an oxide as in claims 6 and 7, and the glasses will inherently have a dissolution rate as in claim 9 and controlled release as in claim 10. Gilchrist et al (page 4, line 32), as well as Burnie et al (page 244, right col, third complete paragraph), and if needed Beaver et al, suggest fibers as in claim 12. The methods of claims 18 and 19 are suggested by Burnie et al and Gilchrist et al disclosing use of the glass as an implant, and Gilchrist et al disclosing (page 9, lines 29-31) the glass dissolving to provide a metal ion concentration in aqueous medium as in claim 19.

Claim Rejections - 35 USC § 103

Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1, 2, 4-7,

9, 10, 12, 18 and 19 above, and further in view of Ducheyne et al (5,811,302).

Claim 13 requires glass fibers sintered together to form a mat. Claim 14 requires glass particles, which are sintered together in claim 15, and are of a specific size in claim 16.

Ducheyne et al disclose (col 4, lines 1-10) sintering glass particles (powder) and binder in a slurry to form a porous substrate for cell culture.

It would have been obvious to form the glass of Burnie et al, when modified as set forth above, as a sintered non-woven mat or sintered particles in view of Burnie et al disclosing (page 244, right col in the paragraph noted above) various forms including powder, fiber and woven cloth, and Gilchrist et al disclosing glass wool (page 4, line 15), and Ducheyne et al disclosing sintering a slurry containing glass powder and binder. A powder will have a particle size within the range of claim 16.

(10) Response to Argument

RESPONSE TO 35 USC 112 REJECTION

Appellants urge that the specification supports claim 18, and refers to sections of the specification as disclosing using the claimed glass matrix for cell growth. However, the claims per se must be clear and definite without relying on the

specification for definiteness and clarity. The metes and bounds of the invention are provided by the claims and not the specification. The claim is confusing by requiring a method without setting forth steps that will perform a method. Merely providing the substrate of claim 1 does not constitute a method that will encourage growth of tissue.

In responding to the rejection of claim 19, appellants also refer to sections of the specification as describing how the method can be performed. This argument is unpersuasive for the same type of reason as set forth above in regard to claim 18. The step of delivering metal ions or boron has not been related to other steps required to encourage tissue growth to make clear how the step of the claim functions to encourage tissue growth.

RESPONSE TO 35 USC 103 REJECTION

Appellants urge that Burnie et al do not disclose a water-soluble glass containing boron or metal ions as claimed. However, the rejection is not based on Burnie et al alone, but on Burnie et al in view of the Gilchrist et al reference which suggests boron and metal ions in a water-soluble glass as claimed for cell growth.

It is granted as urged by appellants that sodium disclosed by Burnie et al is not a metal disclosed in the specification and the claims require a metallic ion that confers either

antimicrobial protection or enhanced cell growth, or both. However, Gilchrist et al disclose magnesium as an antimicrobial (page 15, line 10) and silver (page 9, lines 24-33) for controlled release, and these are metals disclosed in the present specification.

Appellants urge that there is no disclosure or suggestion in Gilchrist et al that the metal and boron-containing water-soluble glass is suitable for cell growth. However, Gilchrist et al disclose using the glass for orthopaedic implants and tissue engineering applications (page 17, lines 20-21). These applications require cell growth in contact with the glass as is apparent from Burnie et al disclosing using C.R.G. for *in vivo* bone healing repair (page 246, conclusion). Gilchrist et al further disclose (page 1, lines 17-23) soluble phosphate based glass as having good biocompatibility and its use to release metals at a wound site. Healing of a wound requires cell growth. Thus, it is clear that Gilchrist et al consider the glass suitable for cell growth, or Gilchrist et al would not have suggested its use as an implant, for tissue engineering and to release metals at a wound site. As is apparent from instant claim 12, the present invention encompasses water-soluble fibers as disclosed by Gilchrist et al.

Appellants urge that metals of the claimed invention are generally considered toxic to the human body, and addition of the metal ions to water-soluble glass stimulated rather than disrupted cell growth. However, Gilchrist et al disclosing using the metal-containing water soluble glass as an implant, for tissue engineering and to release metals at a wound site, suggests that toxicity is not of a sufficient level to make the glass unsuitable for cell growth.

In regard to the rejection of claims 13-16, appellants urge the adding Ducheyne et al does not suggest the claimed cell culture growth substrate that comprises the water-soluble glass. However, the references applied to claims 1, 2, 4-7, 9, 10, 18 and 19 above suggest the claimed water-soluble glass as a cell growth substrate.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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